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**Supplemental Response**

Serial No.: 10/728,439

Confirmation No.: 9418

Filed: 5 December 2003

For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS

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**Remarks**

The Advisory Action mailed June 4, 2008 has been received and reviewed. Reconsideration and withdrawal of the rejections are respectfully requested.

**The Amendments to Claims 53 and 55**

Applicants respectfully submit that there is sufficient written description support for the previously amended claims 53 and 55 throughout the specification. See, for example, page 4, lines 16-29, page 10, lines 4-12, page 13, lines 5-10, page, page 13, lines 21-24, and the general discussion of polymers at pages 13-15.

**The 35 U.S.C. §103 Rejection**

The Examiner rejected claims 7-9 and 12 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358). The Examiner rejected claim 10 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and further in view of Ahmed et al. (U.S. Patent No. 6,458,877). The Examiner rejected claims 19-39, 42-45, 48-50, 53, 55, and 58-60 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and further in view of Takemori et al. (U.S. Patent No. 5,075,373). The Examiner rejected claims 40 and 41 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and Takemori et al. (U.S. Patent No. 5,075,373) and further in view of Ahmed et al. (U.S. Patent No. 6,458,877). The Examiner rejected claims 1-4, 6, and 75 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and further in view of Laurin et al. (U.S. Patent No. 4,603,152). The Examiner rejected claim 5 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and Laurin et al. (U.S. Patent No. 4,603,152) and further in view of Ahmed et al. (U.S. Patent No. 6,458,877). The Examiner rejected claims 13-18 under 35 U.S.C. §103 as being unpatentable

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over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and Laurin et al. (U.S. Patent No. 4,603,152) and further in view of Yan et al. (U.S. Patent Publication No. 2003/0185889). These rejections are respectfully traversed.

As previously mentioned, Highgate discloses a polymeric composition which has sealant and preferably also adhesive properties. "According to one aspect of the present invention the polymeric composition according to the invention may be suitable for use as a protective dressing simply having sealant properties without any adhesive properties and it has been found that it is sometimes desirable to separate these functions. In the case where, for example, the dressing is in the form of a sealing ring used in conjunction with a drainage bag or pouch then a separate adhesive material or a mechanical securing aid would be employed" (column 3, lines 1-10, emphasis added). Applicants previously interpreted this to mean that whether it has adhesive properties or not, the polymeric composition of Highgate needs to "seal" (or, in Applicants' terms "adhere") to the skin of a patient. Upon further evaluation, it appears (although it is not entirely clear) that the polymeric composition of Highgate may not need to seal (in and of itself) to skin; rather, broadly interpreted, Applicants appreciate that the composition could possibly be nonadherent (per se) and something could hold the composition in place by, e.g., a mechanical securing aid.

Even with such a broad interpretation of Highgate, there is no teaching or suggestion in Highgate (or any motivation provided by any of the other documents cited by the Examiner) to make a nonadherent composition that includes the recited bioactive agent. Highgate is not concerned with putting active agents (such as antimicrobial agents) into adhesives, or nonadhesives. Highgate is directed to forming a sealant, such as a sealing ring that is particularly suitable for use with drainage appliances such as ostomy appliances.

In contrast, Asmus is directed to a gel of swollen hydrocolloid dispersed in a pressure sensitive adhesive matrix. There would be no reason to modify Asmus (or any motivation provided by any of the other documents cited by the Examiner) to make a nonadherent composition.

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The only motivation one would have to combine Highgate and Asmus, in either order, would result from hindsight reasoning. The U.S. Supreme Court has cautioned against analysis involving hindsight reasoning in *KSR Int'l co. v. Teleflex Inc.*, 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 USPQ2d (BNA) 1385 (2007), stating, "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (167 L.Ed.2d at 725, citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'" (383 U.S., at 36, quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964))).

Reconsideration and withdrawal of these rejections are respectfully requested.

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It is respectfully submitted that the pending claims 1-10, 12-45, 48-50, 53-55, 58-60, and 75 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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June 19, 2008

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19th day of June, 2008, at 5:08pm (Central Time).

By:

Name:

Sam E. Wiggant